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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,051	09/23/2003	Kyle J. Lindstrom	54913US115	3999

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EXAMINER	
HUANG, EVELYN MEI	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,051	LINDSTROM, KYLE J.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 15-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 15-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 15-17 are pending. Claims 1-14 have been canceled according to the preliminary amendment filed on 11-4-2003.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant 'inducing cytokine biosynthesis' embraces both abnormal and normal cytokine biosynthesis. The latter would have no physio-pathological effect correlated to diseases or disorders that a patentable utility would be found in the treatment thereof. Furthermore, recitation of the mechanism without the end result as in the instant would have no utility and would be rejected under 101 as follows.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention lacks patentable utility for reasons set forth in paragraph 2 above.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The method of inducing cytokine biosynthesis reaches out to activities/conditions/diseases mediated by cytokine not yet identified.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. ***.

a. *Nature of the invention.*

The instant invention is drawn to a sulfonamide substituted imidazoquinoline for inducing cytokine biosynthesis in an animal.

b. *State of the prior art and the level of the skill in the art.*

According to Stedman's Medical Dictionary, cytokine is a general term for any of numerous hormonelike, low molecular-weight proteins, secreted by various cell types, including interferon, interleukin, lymphkine and chemokines etc. While broad spectrum of activities have been attributed to the cytokines, there is only limited understanding of the mechanisms that lead to one activity over another when a specific cytokine is involved in a specific biological reaction (Cohen et al . American Journal of Clinical Pathology 1996, 105(5):589-598, abstract). At the

time of the invention, little is known about the true roles played by chemokines in normal and disease physiology (Rollins BJ. Blood, 1997, 90(3): 909-928, page 920, Conclusions).

Synthetic inducers of interferon are known (Fleming, 3692907, column 23, claim 32). Iimidazo[4,5-c]quinolin-4-amine derivatives are also known to induce interferon biosynthesis (Gerster, 5266575, columns 9-10, PTO-1449). Certain imidazo[4,5-c] quinoline compounds have been shown to induce TNF and IL-1 production (Testerman, abstract, PTO-1449). However, a compound effective in inducing cytokines of all types has not been described. At the time of the invention, there is only limited understanding of the mechanisms that lead ot one activity over another when a specific cytokine is involved in a specific biological reaction.

The level of the skill in the cytokine biosynthesis art is high.

c. *Predictability/unpredictability of the art.*

The high degree of unpredictability is well recognized in the cytokine biosynthesis art. A slight change in the structure of the compound would drastically change its biological activity as evidenced in the different values of structurally similar compounds in the interferon bioassay and the different anti-viral activities by the same compounds in the type II Herpes simplex-infected guinea pigs (Gerster, columns 9-10). Structurally similar imidazo[4,5-c] quinoline compounds have different profiles in the induction of the different cytokines (Testerman, page 367, 368, Table 1 and Table 2). Furthermore, a correlation between the in vitro data and in vivo activity has not been established, as the dose responses for given effects in vitro may not be relevant in vivo (Rollins, page 909, column 2).

d. *Amount of guidance/working examples.*

The preparation of the inventive compound has been described (Example 236). The ability of the example compounds to induce interferon and TNF in human blood cells is shown on pages 126-133 of the specification. No in vivo procedures are described.

e. *Breadth of the claims.*

Applicant's assertion that the inventive compound is an effective inducers of all types of cytokines involving in all the broad spectrum of activities, and reaching out into activities/conditions/diseases not yet identified, does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability and the working examples limiting to induction of interferon and TNF (paragraphs c, d above).

f. *Quantitation of undue experimentation.*

Since insufficient guidance and teaching have been provided by the specification (paragraphs c-e above), one of ordinary skill in the art, even with high level of skill, is unable to use the instant compound as claimed without undue experimentation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being obvious over Crooks (6331539, PTO-1449, having an effective filing date 6-10-1999, therefore it is available as prior art under 102(e); this is issued on 12-18-2001, which is before the instant priority date of 12-21-2001, and is available as prior art under 102(a)).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Crooks generically discloses and claims an interferon inducing sulfonamide and imidazoquinoline compound, composition and method of use thereof (claims 1-23, 25-31), which encompasses the instant compound, composition and method of use. Specific compounds are described and claimed (claim 24).

Crooks' N-[4-(4-amino-2-butyl-1-H-imidazol[4,5-c]quinoline-1-butyl]-1-methaneulfonamide (Example 6, claim 24) has a 2-butyl instead of the instant 2-ethyl as R2.

However, Crooks teaches that the preferred alkyl of R2 has 1-4 carbon atoms (claim 8)

At the time of the invention, one of ordinary skill in the art would be motivated to replace the prior art butyl with its homologus ethyl, which is within the preferred genus of C1-4-alkyl, to arrive at the instant invention, with the reasonable expectation of obtaining an additional interferon-inducing compound.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 15-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6331539. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons set forth in paragraph 4 above.

9. Claim 17 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 29, 32, 35, 38-43 of copending Application No. 10/027272 (CIP of 6331539; wherein the method of inducing cytokine biosynthesis is claimed). Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons set forth in paragraph 6 above for U.S. Patent No. 6331539.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 15, 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 33 of copending Application No. 10/166321 (CIP of 6331539; wherein the subgenus of compound encompassing the instant is claimed). Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons set forth in paragraph 6 above for U.S. Patent No. 6331539.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang
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Art Unit 1625